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Modified Form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)	Application Number	10/517,135
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	Examiner Name	Gyan Chandra
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**U.S. PATENT DOCUMENTS**

Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
*A3	6,288,301 B1	09/11/01	Nardi et al.	800	18		
*A4	6,558,952 B1	05/06/03	Parikh et al.	435	384		
*A5	6,899,883 B2	05/31/05	Dupre	424	198.1		
*A6	6,989,148 B2	01/24/06	Dupre	424	198.1		
*A7	6,992,060 B2	01/31/06	Brand	514	2		
*A8	7,037,504 B2	05/02/06	Magil et al.	242	198.1		

**U.S. PUBLISHED APPLICATION DOCUMENTS**

Exam Initials	Cite No.	U.S. Published Application No.	Published Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
*A9	2002/0081285 A1	06/27/02	Parikh et al.	424	93.21		
*A10	2002/0119146 A1	08/29/02	Dupre	424	93.21		
*A11	2003/0083259 A1	05/01/03	Efendic et al.	514	12		
*A12	2003/0119734 A1	06/26/03	Flink et al.	514	12		
*A14	2003/0224983 A1	12/04/03	Nielsen	514	12		
*A15	2004/0023885 A1	02/05/04	Brand et al.	514	12		
*A16	2004/0037818 A1	02/26/04	Parikh et al.	424	93.21		
*A17	2004/0209801 A1	10/21/04	Brand et al.	514	12		
*A18	2004/0209816 A1	10/21/04	Parikh et al.	514	12		
*A19	2004/0229810 A1	11/18/04	Cruz	514	14		
*A20	2004/0266682 A1	12/30/04	Cruz	514	12		
*A21	2005/0222221 A1	10/06/05	Demuth et al.	514	365		
*A22	2006/0189520 A1	08/24/06	Brand et al.	514	12		
*A23	2006/0234373 A1	10/19/06	Rabinovitch et al.	435	325		
*A24	2006/0234932 A1	10/19/06	Brand	514	12		

FOREIGN PATENT DOCUMENTS					
Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes No
	B1	EP 0 507 555 B1	AMERICAN HOME PRODUCTS CORP.	10/07/92	
	B2	WO 95/19785	RESEARCH TRIANGLE PHARMACEUTICALS	07/27/95	
	B3	WO 95/31214	LONDON HEALTH SCIENCES	11/23/95	
	B4	WO 00/44400	GENERAL HOSPITAL CORPORATION	08/03/00	
	B5	WO 02/12452 A2	CURIS INC.	02/14/02	
	B6	WO 02/055152 A2	WARATAH PHARMACEUTICALS	07/18/02	
	B7	WO 03/040310 A2	WARATAH PHARMACEUTICALS	05/15/03	
	B8	WO 03/100024 A2	WARATAH PHARMACEUTICALS	12/04/03	
	B9	WO 03/103701 A1	WARATAH PHARMACEUTICALS	12/18/03	
	B10	WO 2004/037195 A2	WARATAH PHARMACEUTICALS	05/06/04	
	B11	WO 2004/045640 A1	WARATAH PHARMACEUTICALS	06/03/04	
	B12	WO 2004/096853 A1	WARATAH PHARMACEUTICALS	11/11/04	
	B13	WO 2004/105780 A2	WARATAH PHARMACEUTICALS	12/09/04	
	B14	WO 2005/072045 A2	WARATAH PHARMACEUTICALS	08/11/05	
	B15	WO 2006/002532 A1	WARATAH PHARMACEUTICALS	01/12/06	
	B16	WO 2007/041833 A1	WARATAH PHARMACEUTICALS	04/19/07	
	B17	WO 2007/062531 A1	WARATAH PHARMACEUTICALS	06/07/07	
	B18	WO 2007/095737 A1	WARATAH PHARMACEUTICALS	08/30/07	
OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS					
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.			
	C9	Adams et al., "Insulin-like growth factor-I promotes successful fetal pancreas transplantation in the intramuscular site", <i>Surgery</i> , 116:751-757 (1994)			
	C10	Ahmed et al., "High and Low Affinity Receptors Mediate Growth Effects of Gastrin and Gastrin-Gly on DLD-1 Human Colonic Carcinoma Cells", <i>FEBS Letters</i> , 556:199-203 (2004)			
	C11	Aly et al., "Short-term infusion of glycine-extended gastrin <sub>17</sub> stimulates both proliferation and formation of aberrant crypt foci in rat colonic mucosa", <i>International Journal Cancer</i> , 94:307-313 (2001)			
	C12	Aly et al., "Gastrins, cholecystokinins and gastrointestinal cancer", <i>Biochimica et Biophysica Acta</i> , 1704:1-10 (2004)			
	C13	Araki et al., "Stability of Recombinant Epidermal Growth Factor in Various Solutions", <i>Chem. Pharm. Bull.</i> , 37(2):404-406 (1989)			
	C14	Baggio et al., "Sustained Expression of Exendin-4 Does Not Perturb Glucose Homeostasis, b-Cell Mass, or Food Intake in Metallothionein-Preproexendin Transgenic Mice", <i>J Biol Chem</i> , 275:34472-34477 (2000)			
	C15	Baggio et al., "Therapeutic approaches to preserve islet mass in type 2 diabetes", <i>Annual Review of Medicine</i> , 57:265-281 (2006)			
	C16	Baldwin, G.S., "The role of gastrin and cholecystokinin in normal and neoplastic gastrointestinal growth", <i>J. Gastroenterol. Hepatol.</i> , 10(2):215-232 (1995)			
	C17	Baldwin et al., "Measurement of Gastrin and Transforming Growth Factor $\alpha$ Messenger RNA Levels in Colonic Carcinoma Cell Lines by Quantitative Polymerase Chain Reaction", <i>Cancer Research</i> , 52:2261-2267 (1992)			

FOREIGN PATENT DOCUMENTS					
Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes No
	C18	Beger et al., "RS-61443 Prevents Microvascular Rejection of Pancreatic Islet Xenografts", <i>Transplantation</i> , 63(4):577-582 (1997)			
	C19	Berendsen, H.J.C., "A glimpse of the Holy Grail?", <i>Science</i> , 282:642-643 (1998)			
	C20	Bonato et al., "Guinea Pig 33-Amino Acid Gastrin", <i>Life Science</i> , 39:959-964 (1986)			
	C21	Boniface et al., "Clearance Rate, Half-Life, and Secretory Potency of Human Gastrin-17-I in Different Species", <i>Gastroenterology</i> , 71(2):291-294 (1976)			
	C22	Bosch et al., "Epidermal Growth Factor Mimics Insulin Effects in Rat Hepatocytes", <i>Biochem J</i> , 239:523-530 (1986)			
	C23	Bower et al., "The inhibition of gastric acid secretion by epidermal growth factor", <i>Experientia</i> , 31(7):825-826 (1975)			
	C24	Brand et al., "Differential Gastrin Gene Expression in Rat Gastrointestinal Tract and Pancreas during Neonatal Development", <i>J. Biol. Chem.</i> , 263(11):5341-5347 (1988)			
	C25	Brand et al., "Gastrin Gene Expression and Regulation in Rat Islet Cell Lines", <i>J. Biol. Chem.</i> , 263:16597-16603 (1994)			
	C26	Brand et al., "Pharmacological Treatment of Chronic Diabetes by Stimulating Pancreatic b-Cell Regeneration with Systemic Co-administration of EGF and Gastrin", <i>Pharmacology &amp; Toxicology</i> , 91(6):414-420 (2002)			
	C27	Brand et al., "Prolonged Efficacy of Islet Neogenesis Therapy with Gastrin and TGF $\alpha$ in Mature Rats with Preexisting Diabetes", <i>Diabetes</i> , 50(Suppl 2):A338 (Abstract) (2001)			
	C28	Brenna et al., "Trophic effect of gastrin on the enterochromaffin like cells of the ratstomach: establishment of a dose response relationship", <i>Gut</i> , 33(10):1303-1306 (1992)			
	C29	Burgess et al., "Murine Epidermal Growth Factor: Structure and Function", <i>Biochemistry</i> , 27:4977-4985 (1988)			
	C30	Burgess et al., "Two Forms of Murine Epidermal Growth Factor: Rapid Separation by Using Reverse-Phase HPLC", <i>Proc. Natl. Acad. Sci. U.S.A.</i> , 79:5753-5757 (1982)			
	C31	Calnan et al., "Potency and Stability of C Terminal Truncated Human Epidermal Growth Factor", <i>Gut</i> , 47:622-627 (2000)			
	C32	Campbell et al., "Structure-function relationships in epidermal growth factor (EGF) and transforming growth factor-alpha (TGF-alpha)", <i>Biochem. Pharmacol.</i> , 40:35-40 (1990)			
	C33	Carlsson et al., "Gastrin and gastric enterochromaffin-like cell carcinoids in the rat", <i>Digestion</i> , 47(Suppl 1):17-23, "Discussion", pp 49-52 (1990)			
	C34	Carpenter et al., "Human Epidermal Growth Factor and the Proliferation of Human Fibroblasts", <i>J. Cell Physiol</i> , 88:227-237 (1976)			
	C35	Carver et al., "A high resolution 1H NMR study of the solution structure of human epidermal growth factor", <i>FEBS Lett.</i> , 205(1):77-81 (1986)			
	C36	Chatenoud, L., "Restoration of Self-Tolerance Is a Feasible Approach to Control Ongoing Beta-Cell Specific Autoreactivity: Its Relevance for Treatment in Established Diabetes and Islet Transplantation", <i>Diabetologia</i> , 44:521-536 (2001)			
	C37	Chatenoud et al., "Anti-CD3 Antibody Induces Long-Term Remission of Overt Autoimmunity in Nonobese Diabetic Mice", <i>Proc Natl Acad Sci U S A</i> , 91:123-127 (1994)			
	C38	Chen et al., "Time course of hypertrophic and ultrastructural responses of rat stomach enterochromaffin-like cells to sustained hypergastrinemia", <i>Cell Tissue Res</i> , 284(1):55-63 (1994)			
	C39	Clare et al., "Production of Mouse Growth Factor in Yeast: High-Level Secretion Using Pichia pastoris Strains Containing Multiple Gene Copies", <i>Gene</i> , 105:205-212 (1991)			

	C40	Conreas et al., "The Effects of Gastrin, Epidermal Growth Factor, and Somatostatin on DNA Synthesis in a Small Intestinal Crypt Cell Line (IEC-6) (42484)", <i>Proc. Soc. Exp. Biol. Med.</i> , 184(3):307-311 (1987)
	C41	Cooke et al., "The solution structure of human epidermal growth factor", <i>Nature</i> , 327:339-341 (1987)
	C42	Cras-Meneur et al., "Epidermal growth factor increases undifferentiated pancreatic embryonic cells in vitro: a balance between proliferation and differentiation", <i>Diabetes</i> , 50:1571-1579 (2001)
	C43	Crean et al., "Parietal cell hyperplasia induced by the administration of pentagastrin (ICI 50,123) to rats", <i>Gastroenterology</i> , 57(2):147-155 (1969)
	C44	Creutzfeldt et al., "Is hypergastrinaemia dangerous to man?", <i>Scand J Gastroenterol Suppl.</i> , 180:179-191 (1991)
	C45	Database GenCore on EST, ID AAP61038, Billing-Medel et al., "Reagents and methods useful for detecting diseases of the breast", <i>Gene Sequence</i> (2003)
	C46	Database GenCore on EST, ID I52995, Saggi et al., "Cloning and Sequencing of the Rat Preproepidermal Growth Fact cDNA", <i>Gene Sequence</i> (2003)
	C47	Datta et al., "Ionizing radiation activates transcription of the EGRI gene via CArG elements", <i>Proc. Natl. Acad. Sci. USA</i> , 89:10149-10153 (1992)
	C48	Dembinski et al., "Trophic Action of Epidermal Growth Factor on the Pancreas and Gastroduodenal Mucosa in Rats", <i>J Physiol (Lond)</i> , 325:35-42 (1982)
	C49	Dembinski et al., "Stimulation of Pancreatic Growth by Secretin, Caerulein, and Pentagastrin", <i>Endocrinology</i> , 106(1):323-328 (1980)
	C50	Di Lorenzo et al., "Involvement of growth factor receptors of the epidermal growth factor receptor family in prostate cancer development and progression to androgen independence", <i>Clin. Prostate Cancer</i> , 2(1):50-57 (2003)
	C51	DiAugustine et al., "Evidence for Isoaspartyl (Deamidated) Forms of Mouse Epidemal Growth Factor", <i>Analytical Biochemistry</i> , 165:420-429 (1987)
	C52	Dockray, G.J., "Gastrin", <i>Best Practice &amp; Research Clinical Endocrinology &amp; Metabolism</i> , 18(4):555-568 (2004)
	C53	Dockray, G.J., "Gastrin and gastric epithelial physiology", <i>J Physiol.</i> , 518(Pt.2):315-324(1999)
	C54	Dockray et al., "Immunochemical Characterization of Gastrin in Pancreatic Islets of Normal and Genetically Obese Mice", <i>J Endocrinol</i> , 72:143-151(1977)
	C55	Dockray et al., "Postsecretory Processing of Heptadecapeptide Gastrin: Conversion to C-Terminal Immunoreactive Fragments in the Circulation of the Dog", <i>Gastroenterology</i> , 83:224-232 (1982)
	C56	Drumm et al., "Urogastrone/epidermal growth factor in treatment of congenital microvillous atrophy", <i>Lancet</i> , 1(8577):111-112 (1988)
	C57	Dupre et al., "Effects of Secretin, Pancreozymin, or Gastrin on the Response of the Endocrine Pancreas to Administration of Glucose or Arginine in Man", <i>Journal of Clinical Investigation</i> , 48:745-757 (1969)
	C58	Durrant et al., "Co-stimulation of Gastrointestinal Tumour Cell Growth by Gastrin, Transforming Growth Factor $\alpha$ and Insulin Like Growth Factor-1", <i>Brit. J. Cancer</i> , 63:67-70 (1991)
	C59	Efrat, S., "Prospects for gene therapy of insulin-dependent diabetes mellitus", <i>Diabetologia</i> , 41:1401-1409 (1998)
	C60	Elder et al., "Effect of urogastrone on gastric secretion and plasma gastrin levels in normal subjects", <i>Gut</i> , 16(11):887-893 (1975)
	C61	Elder et al., "Effect of urogastrone in the Zollinger-Ellison syndrome", <i>The Lancet</i> , 2(7932):424-427 (1975)
	C62	Ennis et al., "The EGF receptor system as a target for antitumor therapy", <i>Cancer Invest.</i> , 9(5):553-562 (1991)

C63	Ferrara et al., "Molecular and Biological Properties of the Vascular Endothelial Growth Factor Family of Proteins", <i>Endocr Rev</i> , 13(1):18-32 (1992)
C64	Gasslander et al., "Trophic Effects by Epidermal Growth Factor on Duodenal Mucosa and Exocrine Pancreas in Rats", <i>Eur Surg Res</i> , 29:142-149 (1997)
C65	George-Nascimento et al., "Characterization of Recombinant Human Epidermal Growth Factor Produced in Yeast", <i>Biochemistry</i> , 27:797-802 (1988)
C66	George-Nascimento et al., "Replacement of a Labile Aspartyl Residue Increases the Stability of Human Epidermal Growth Factor", <i>Biochemistry</i> , 29:9584-9591 (1990)
C67	Goodlad et al., "Comparison of the Mitogenic Activity of Human Epidermal Growth Factor I-53 and Epidermal Growth Factor I-48 in vitro and in vivo", <i>Clinical Sciences</i> , 91:503-507 (1996)
C68	Goodlad et al., "Intravenous but not intragastric urogastrone-EGF is trophic to the intestine of parenterally fed rats", <i>Gut</i> , 28:573-582 (1987)
C69	Guglietta et al., "Effect of h-EGF and h-EGF 1-48 on histamine-stimulated gastric acid secretion in rats and monkeys", <i>J. Physiol Paris</i> , 87:343-347 (1993)
C70	Guglietta et al., "Clinical applications of epidermal growth factor", <i>Eur. J. Gastroenterol. Hepatol.</i> , 7(10):945-950 (1993)
C71	Hakanson et al., "Hypergastrinaemia produces trophic effects in stomach but not in pancreas and intestines", <i>Regul. Pept.</i> , 13:225-233 (1986)
C72	Hayashi et al., "A Sensitive Enzyme Immunoassay for Human Epidermal Growth Factor. Determination of HEGF in Human Serum and Urine and Pharmacokinetics in Mouse", <i>J Pharmacobiodyn</i> , 12:410-415 (1989)
C73	Hayek et al., "Growth Factor/Matrix-Induced Proliferation of Human Adult Beta-Cells", <i>Diabetes</i> , 44:1458-1460 (1995)
C74	Heath et al., "A synthetic approach to structure-function relationships in the murine epidermal growth factor molecule", <i>Proc. Natl. Acad. Sci. U.S.A.</i> , 83:6367-6371 (1986)
C75	Herbst, R.S., "Review of epidermal growth factor receptor biology", <i>Int. J. Radiat. Oncol. Biol. Phys.</i> , 59(2 Suppl.):21-26 (2004)
C76	Herbst et al., "Epidermal growth factor receptors as a target for cancer treatment: the emerging role of IMC-C225 in the treatment of lung and head and neck cancers", <i>Semin. Oncol.</i> , 29(1, Suppl. 4):27-36 (2002)
C77	Herold et al., "Prevention of Autoimmune Diabetes With Nonactivating Anti-CD3 Monoclonal Antibody", <i>Diabetes</i> , 41:385-391 (1992)
C78	Herold et al., "Anti-CD3 Monoclonal Antibody in New-Onset Type 1 Diabetes Mellitus", <i>N Engl J Med</i> , 346(22):1692-1698 (2002)
C79	Herold et al., "A Single course of Anti-CD3 Monoclonal Antibody hOKT3y1(Ala-Ala) Results in Improvement in C-Peptide Responses and Clinical Parameter for at Least 2 Years After Onset of Type 1 Diabetes", <i>Diabetes</i> , 54:1763-1769 (2005)
C80	Hollande et al., "In Vitro Secretion of Gastrin, Insulin, and Glucagon in Tissue Cultures of Pancreas From a Child with Neonatal Intractable Hypoglycemia", <i>Gastroenterology</i> , 71(2):255-262 (1976)
C81	Hollenberg et al., "Epidermal Growth Factor-Urogastone: Biological Activity and Receptor Binding of Derivatives", <i>Molecular Pharmacology</i> , 17:314-320 (1980)
C82	Ito et al., "Structural analysis of the gene encoding human gastrin: The large intron contains an <i>Alu</i> sequence", <i>Proc Natl. Acad. Sci. USA</i> , 81(15):4662-4666 (1984)
C83	Jensen, R., "Gastrinoma as a model for prolonged hypergastrinemia in the human", in <i>Gastrin</i> , Chapter 29, pp 373-393, Raven Press Ltd., New York (1993)
C84	Juhl et al., "Systemic Treatment With Recombinant Human Epidermal Growth Factor Accelerates Healing of Sclerotherapy-Induced Esophageal Ulcers and Prevents Esophageal Stricture Formations in Pigs", <i>Dig Dis Sci</i> , 39:2671-2678 (1994)

	C85	Karnes, Jr., W.E., "Epidermal Growth Factor and Transforming Growth Factor-alpha", in <i>Gut Peptides: Biochemistry and Physiology</i> , Chapter 20, pp. 553-586, Raven Press Ltd., New York (1994)
	C86	Keiser et al., "Hemodynamic effects of epidermal growth factor in conscious rats and monkeys", <i>Proc. Natl. Acad. Sci. U.S.A.</i> , 93:4957-4961 (1996)
	C87	Keymeulen et al., "Insulin Needs After CD3-Antibody Therapy in New-Onset Type 1 Diabetes", <i>New England Journal of Medicine</i> , 352:2598-2608 (2005)
	C88	Kim et al., "EGF receptor signaling in prostate morphogenesis and tumorigenesis", <i>Histol. Histopathol.</i> , 14(4):1175-1182 (1999)
	C89	Koch et al., "Molecular Species of Epidermal Growth Factor Carrying Immunosuppressive Activity", <i>Journal of Cellular Biochemistry</i> , 25:45-59 (1984)
	C90	Koffman et al., "Effect of urogastrone on gastric secretion and serum gastrin concentration in patients with duodenal ulceration", <i>Gut</i> , 23(11):951-956 (1982)
	C91	Konturek et al., "Release and action of epidermal growth factor on gastric secretion in humans", <i>Scand. J. Gastroenterol.</i> , 24(4):485-492 (1989)
	C92	Konturek et al., "Comparison of Organ Uptake and Disappearance Half-Time of Human Epidermal Growth Factor and Insulin", <i>Regul Pept</i> , 30:137-148 (1990)
	C93	Kopin et al., "The role of the cholecystokinin-B/gastrin receptor transmembrane domains in determining affinity for subtype-selective ligands", <i>J Biol Chem</i> , 270(10):5019-5023 (1995)
	C94	Korc et al., "Regulation of Protein Synthesis in Normal and Diabetic Rat Pancreas by Cholecystokinin", <i>Am J Physiol</i> , 241:G116-G121 (1981)
	C95	Korc, M.J., "Islet Growth Factors: Curing Diabetes and Preventing Chronic Pancreatitis?", <i>Clin. Invest.</i> , 92:1113-1114 (1993)
	C96	Kuo et al., "Pharmacokinetic Evaluation of Two Human Epidermal Growth Factors (hEGF51 and hEGF53) in Rats", <i>Drug Metabolism and Description</i> , 20(1):23-30 (1991)
	C97	Larsson et al., "Pancreatic gastrin in foetal and neonatal rats", <i>Nature</i> , 262:609-610 (1976)
	C98	Lima-Leite et al., "Synthesis and Biological Activities of the Human Gastrin analogs", <i>Brazilian Journal of Medical and Biological Research</i> , 29(10):1253-1263 (1996)
	C99	Marti et al., "Biological effects of epidermal growth factor, with emphasis on the gastrointestinal tract and liver: an update", <i>Hepatology</i> , 9(1):126-138 (1989)
	C100	Martindale: The Extra Pharmacopoeia, 13 <sup>th</sup> Edition, The Pharmaceutical Press, London, pp. 869-898 (1993)
	C101	Maton et al., "Long-Term Efficacy and Safety of Omeprazole in Patients With Zollinger-Ellison Syndrome: a Prospective Study", <i>Gastroenterology</i> , 97:827-836 (1989)
	C102	Merchant et al., "Epidermal Growth Factor Stimulation of the Human Gastrin Promoter Requires Sp1", <i>J Biol Chem</i> , 270(11):6314-6319 (1995)
	C103	Merlino, G., "Epidermal growth factor receptor regulation and function", <i>Semin. Cancer Biol.</i> , 1:277-284 (1990)
	C104	Morley et al., "Structure-Function Relationships in the Active C-Terminal Tetrapeptide Sequence of Gastrin", <i>Nature</i> , 207:1356-1359 (1965)
	C105	Morley, J.S., "Synthesis of Human Gastrin(I) and the Biological Properties of Analogues", in <i>Peptides</i> , pp 226-234, North Holland Publishing Co., Amersterdam (1967)
	C106	Morley et al., "Polypeptides. Part IX. Variations of the Methionyl Position in the C-terminal Tetrapeptide Amide Sequence of the Gastrins", <i>J. Chem. Soc.</i> , 726-733 (1968)
	C107	Mottram et al., "Remission and Pancreas Isograft Survival in Recent Onset Diabetes NOD Mice After Treatment with Low-Dose Anti-CD3 Monoclonal Antibodies", <i>Transplant Immunology</i> , 10:63-72 (2002)
	C108	Normanno et al., "EGF-related peptides in the pathophysiology of the mammary gland", <i>J. Mammary Gland Biol. Neoplasia</i> , 2(2):143-151 (1997)

	C109	Ohlsson et al., "The Method of Administration of Cholecystokinin Determines the Effects Evoked in the Pancreas", <i>Pancreas</i> , 23(1):94-101 (2001)
	C110	Ohlsson et al., "The Effect of Intermittent Injections of CCK-8S and the CCK-A Receptor Antagonist Devazepide on Cell Proliferation in Exocrine Rat Pancreas", <i>Int J Pancreatol</i> , 24(3):211-218 (1998)
	C111	Ohlsson et al., "Epidermal Growth Factor Induces Cell Proliferation in Mouse Pancreas and Salivary Glands", <i>Pancreas</i> , 14(1):94-98 (1997)
	C112	Orbuch et al., "Prolonged hypergastrinemia does not increase the frequency of colonic neoplasia in patients with Zollinger-Ellison syndrome", <i>Dig. Dis. Sci.</i> , 41(3):604-613 (1996)
	C113	Orkin et al., "Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy" (December 7, 1995)
	C114	Patel et al., "Treatment of non-insulin-dependent diabetes mellitus", <i>Expert Opinion Investig Drugs</i> , 12(4):623-633 (2003)
	C115	Pauwels et al., "Metabolism of Heptadecapeptide Gastrin in Humans Studied by Region-specific Antisera", <i>J. Clin. Invest.</i> , 75:2006-2013 (1985)
	C116	Pearson, W.R., "Empirical Statistical Estimates for Sequence Similarity Searches", <i>J. Mol. Biol.</i> , 276:71-84 (1998)
	C117	Pederson et al., "Effect of Cholecystokinin, Secretin, and Gastric Inhibitory Polypeptide on Insulin Release From the Isolated Perfused Rat Pancreas", <i>Can J Physiol Pharmacol</i> , 57:1233-1237 (1979)
	C118	Pratha et al., "Inhibition of pentagastrin-stimulated gastric acid secretion by pantoprazole and omeprazole in healthy adults", <i>Digestive Diseases and Sciences</i> , 51(1):123-131 (2006)
	C119	Rehfeld et al., "The Effect of Gastrin on Basal- and Glucose-Stimulated Insulin Secretion in Man", <i>J Clin Invest</i> , 52:1415-1426 (1973)
	C120	Rehfeld et al., "The Effect of Gastrin and Cholecystokinin on the Endocrine Pancreas", <i>Frontiers of Hormone Research</i> , 7:107-118 (1980)
	C121	Reilly, J., "Safety profile of the proton-pump inhibitors", <i>Am. J. Health Syst. Pharm.</i> 1:56(23 Suppl 4): S11-S17 (1999)
	C122	Robinson et al., "The international standard for epidermal growth factor (EGF): Comparison of candidate preparations by in vitro bioassays and immunoassays", <i>Growth Factors</i> , 13:163-170 (1996)
	C123	Rooman et al., "Mitogenic effect of gastrin and expression of gastrin receptors in ductlike cells of rat pancreas", <i>Gastroenterology</i> , 121:940-949 (2001)
	C124	Rooman et al., "Effects of gastrin on proliferating and differentiation in regenerating pancreas", <i>Diabetologia</i> , pp 106 (Abstract) (2000)
	C125	Rooth et al., "Prevention of detrimental effect of cyclosporin A on vascular ingrowth of transplanted pancreatic islets with verapamil", <i>Diabetes</i> , 38(Suppl. 1):202-205 (1989)
	C126	Rozengurt et al., "Gastrin, CCK, signaling, and cancer", <i>Annu. Rev. Physiol.</i> , 63:49-76 (2001)
	C127	Ryberg et al., "Trophic Effects of Continuous Infusion of [Leu <sup>15</sup> ]-Gastrin-17 in the Rat", <i>Gastroenterology</i> , 98(1):33-38 (1990)
	C128	Schally et al., "New approaches to therapy of cancers of the stomach, colon and pancreas based on peptide analogs", <i>Cell. Mol. Life Sci.</i> , 61(9):1042-1068 (2004)

	C129	Scheving et al., "Circadian phase-dependent stimulatory effects of epidermal growth factor on deoxyribonucleic acid synthesis in the tongue, esophagus, and stomach of the adult male mouse", <i>Endocrinology</i> , 105:1475-1480 (1979)
	C130	Seva et al., "Growth-Promoting Effects of Glycine-Extended Progastrin", <i>Science</i> , 265:410-412 (1994)
	C131	Shapiro et al., "Combination Therapy With Low Dose Sirolimus and Tacrolimus Is Synergistic in Preventing Spontaneous and Recurrent Autoimmune Diabetes in Non-Obese Diabetic Mice", <i>Diabetologia</i> , 45:224-230 (2002)

	C132	Shapiro et al., "Islet Transplantation in Seven Patients with Type 1 Diabetes Mellitus using a Glucocorticoid-Free Immunosuppressive Regimen", <i>New England Journal of Medicine</i> , 343(4):230-238 (2000)
	C133	Shin et al., "Synthesis and Biological Activity of N-Terminal-Truncated Derivatives of Human Epidermal Growth Factor (h-EGF)", <i>Peptides</i> , 16(2):205-210 (1995)
	C134	"SIGMA, Big Gastrin 1 human", <a href="https://www.sigmaaldrich.com/catalog/search/ProductDetail/SIGMA/G7264">https://www.sigmaaldrich.com/catalog/search/ProductDetail/SIGMA/G7264</a>
	C135	"SIGMA , Leu15-Gastrin 1 human", <a href="http://www.sigmaldrich.com/catalog/search/ProductDetail/ProNo=G9145&amp;Brand=Sigma">http://www.sigmaldrich.com/catalog/search/ProductDetail/ProNo=G9145&amp;Brand=Sigma</a>
	C136	"SIGMA, Designing Custom Peptides", <a href="http://www.sigmalgenosys.com/peptide_design.asp">http://www.sigmalgenosys.com/peptide_design.asp</a> , pp 1 -2
	C137	Simpson et al., "Rat epidermal growth factor: complete amino acid sequence", <i>Eur. J. Biochem.</i> , 153:629-637 (1985)
	C138	Singh et al., "Novel Gastrin Receptors Mediate Mitogenic Effects of Gastrin and Processing Intermediates of Gastrin on Swiss 3T3 Fibroblasts", <i>J. Biol Chem.</i> , 270(15):8429-8438 (1995)
	C139	Sinha et al., "Epidermal growth factor enemas are effective in the treatment of left-sided ulcerative colitis", <i>AGA</i> , (Abstract) (2001)
	C140	Sizemore et al., "Impact of Receptor Downregulation on Clearance of Two Human EGFs With Different Receptor Binding Activity", <i>Peptides</i> , 17(7):1229-1236 (1996)
	C141	Slice et al., "Gastrin and EGF Synergistically Induce Cyclooxygenase2 Expression in Swiss 3T3 Fibroblasts that Express the CCK <sub>2</sub> Receptor", <i>J. Cellular Physiology</i> , 196:454-463 (2003)
	C142	Slover et al., "Prevention of Type I Diabetes and Recurrent Beta-Cell Destruction of Transplanted Islets", <i>Endocr Rev</i> , 18(2):241-258 (1997)
	C143	Soon-Shiong et al., "Long-term reversal of diabetes by the injection of immunoprotected islets", <i>Proc. Natl. Acad. Sci USA</i> , 90(12):5843-5847 (1993)
	C144	Stadil et al., "Preparation of <sup>125</sup> I-Labelled Synthetic Human Gastrin I for Radioimmunoanalysis", <i>Scand J Clin Lab Invest</i> , 30:361-368 (1972)
	C145	Stagsted et al., "Insulinomimetic effect on glucose transport by epidermal growth factor when combined with a major histocompatibility complex class I-derived peptide", <i>J. Biol. Chem.</i> , 268(3):1770-1774 (1993)
	C146	Suarez-Pinzon et al., "Combination Therapy with Epidermal Growth Factor and Gastrin Increases Beta-Cell Mass and Reverses Hyperglycemia in Diabetic NOD Mice", <i>Diabetes</i> , 54:2596-2601 (2005)
	C147	Suarez-Pinzon et al., "Combination therapy with epidermal growth factor and gastrin induces neogenesis of human islet beta cells from pancreatic duct cells and an increase in functional betacell mass", <i>J Clin Endocrinol &amp; Metabolism</i> , 90(6):3401-3409 (2005)
	C148	Sullivan et al., "Epidermal growth factor in necrotizing enteritis [letter]", <i>The Lancet</i> , 338(8758):53-54 (1991)
	C149	Svoboda et al., "Structural characterization and biological activity of recombinant human epidermal growth factor proteins with different N-terminal sequences", <i>Biochimica et Biophysica Acta</i> , 1206:35-41 (1994)
	C150	Taylor et al., "Effect of individual L-amino acids on gastric acid secretion and serum gastrin and pancreatic polypeptide release in humans", <i>Gastroenterology</i> , 83:273-278 (1982)
	C151	Taylor et al., "Serum gastrin in patients with chronic renal failure", <i>Gut</i> , 21(12):1062-1067 (1980)
	C152	Thomas et al., "Role of gastrointestinal hormones in the proliferation of normal and neoplastic tissues", <i>Endocr. Rev.</i> , 24(5):571-599 (2003)
	C153	Tracy et al., "Physiological Properties of a Series of Synthetic Peptides Structurally Related to Gastrin 1", <i>Nature</i> , 204:935-938 (1964)
	C154	"Transition Therapeutics Confirms Effectiveness of Islet Neogenesis Therapy in Reducing Diabetic Symptoms", Transition Therapeutics Press Release, April 17, 2002

	C155	"Transition Therapeutics Inc. Receives Approval to Initiate Phase I Clinical Trial for Islet Neogenesis Therapy", Transition Therapeutics Press Release, September 20, 2002
	C156	"Transition Therapeutics' I.N.T. <sup>TM</sup> Treatment Stimulates Regeneration of Human Insulin-Producing Cells", Transition Therapeutics Press Release, September 26, 2002
	C157	"Transition Therapeutics' I.N.T. <sup>TM</sup> Treatment Increases Survival", Transition Therapeutics Press Release, September 27, 2002
	C158	Unger et al., "The Effects of Secretin, Pancreozymin, and Gastrin on Insulin and Glucagon Secretion in Anesthetized Dogs", <i>Journal of Clinical Investigation</i> , 46(4):630-645 (1967)
	C159	Vinter-Jensen, L., "Pharmacological Effects of Epidermal Growth Factor (EGF) with focus on the urinary and gastrointestinal tracts", <i>APMIS</i> , 107(Suppl. 93):1-42 (1999)
	C160	Vinter-Jensen et al., "Systemic Treatment with Epidermal Growth Factor in Pigs Induces Ductal Proliferations in the Pancreas", <i>Gastroenterology</i> , 113:1367-1374 (1997)
	C161	Walker-Smith et al., "Intravenous epidermal growth factor/urogastrone increases small- intestinal cell proliferation in congenital microvillous atrophy", <i>The Lancet</i> , 2(8466):1239-1240 (1985)
	C162	Wallmark et al., "The Relationship Between Gastric Acid Secretion and Gastric H <sup>+</sup> , K <sup>+</sup> -ATPase Activity", <i>J. Biol. Chem.</i> , 260(25):13681-13684 (1985)
	C163	Walsh et al., "pH dependence of acid secretion and gastrin release in normal and ulcer subjects", <i>J. Clin. Invest.</i> , 55:462-468 (1975)
	C164	Walsh, J., "Gastrin", in <i>Gut Peptides: Biochemistry and Physiology</i> , Chapter 4, pp 75-121, Raven Press Ltd., New York (1994)
	C165	Wang et al., "Intraportal delivery of immunosuppression to intrahepatic islet allograft recipients", <i>Transp. Int.</i> , 8:268-272 (1995)
	C166	Wang et al., "Pancreatic duct cells express gastrin and TGF-alpha during duct to islet-cell differentiation in duct-ligated adult rats", <i>Diabetologia</i> , 39(Supplement 1):A63 (Abstract) (1996)
	C167	Wang et al., "Expression of gastrin and transforming growth factor- $\alpha$ during duct to islet cell differentiation in the pancreas of duct-ligated adult rats", <i>Diabetologia</i> , 40:887-893 (1997)
	C168	Wang et al., "Function and Regulation of Gastrin in Transgenic Mice: A Review", <i>Yale Journal of Biology and Medicine</i> , 65:705-713 (1992)
	C169	Wank, S.A., "Cholecystokinin Receptors", <i>Am J Physiol</i> , 269:G628-G646 (1995)
	C170	Wank et al., "Cholecystokinin Receptor Family. Molecular Cloning, Structure, and Functional Expression in Rat, Guinea Pig, and Human", <i>Ann NY Acad Sci</i> , 713:49-66 (1994)
	C171	Wennberg et al., "Efficacy of Immunosuppressive Drugs in Islet Xenotransplantation", <i>Transplantation</i> , 63(9):1234-1242 (1997)
	C172	Wiborg, O., "Structure of a Human Gastrin Gene", <i>Proc Natl Acad Sci USA</i> , 81:1067-1069 (1984)
	C173	Yamaoka et al., "Development of Pancreatic Islets (Review)", <i>International Journal of Molecular Medicine</i> , 3(3):247-261 (1999)
	C174	Yano et al., "Effects of Intrahepatic Arterial and Intraportal Administration of FK506 on Liver Allograft Survival in Rats", <i>Transpl. Int.</i> , 7(Suppl. 1):S187-S193 (1994)

\* By the waiver of 37 CFR 1.98(a)(2)(ii) copies of the U.S. Patents A3-A8 and U.S. Published Applications A9-A24 are not submitted.

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